

conducted. If, upon retest, the average IgG level per dose of the two samples of the test serial does not meet or exceed that of the reference, or if a retest is not conducted, the serial is unsatisfactory.

[61 FR 51777, Oct. 4, 1996]

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

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AUTHORITY: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.2(d).

SOURCE: 39 FR 16869, May 10, 1974, unless otherwise noted.

§ 114.1 Applicability.

Unless exempted by regulation or otherwise authorized by the Administrator, all biological products prepared, sold, bartered or exchanged, shipped or delivered for shipment in or from the United States, the District of Columbia, any Territory of the United States, or any place under the jurisdiction of the United States shall be prepared in accordance with the regulations in this part. The licensee or permittee shall adopt and enforce all necessary measures and shall comply with all directions the Administrator prescribes for carrying out such regulations.

[52 FR 11026, Apr. 7, 1987, as amended at 56 FR 66784, Dec. 26, 1991]

§ 114.2 Products not prepared under license.

(a) When an establishment license is issued, if biological products which were not prepared in compliance with the regulations are in the establishment, such products shall not be shipped or delivered for shipment or otherwise dealt with as having been prepared under such regulations.

(b) Except as provided in 9 CFR part 103, a biological product shall not be prepared in a licensed establishment unless the person to whom the establishment license is issued holds an unexpired, unsuspended, and unrevoked product license issued by the Administrator to prepare such biological product, or unless the products prepared are subject to the provisions of § 107.2 of this subchapter.

(c) A biological product produced in a USDA-licensed establishment shall be produced under a U.S. Veterinary Biological Product License or a license granted by a State under § 107.2 (referred to as a State biological product license and the products prepared pursuant thereto as State-licensed biological products, including autogenous biologics), but not under both a U.S. Veterinary Biological Product License and a State biological product license. Before a U.S. Veterinary Biological Product License (including a conditional license) is issued, the licensee shall relinquish its State license for that product: *Provided*, That autogenous biologics shall not be subject to this provision when they are prepared in accordance with the provisions of paragraph (c)(5) of this section.

(1) State-licensed biological products (including autogenous biologics) shall only be distributed or shipped intrastate, must not bear a U.S. Veterinary Biologics Establishment License Number, and must not otherwise be represented in any manner as having met the requirements for a U.S. Veterinary Biological Product license. Labeling of State- and USDA-licensed biological products produced in the same establishment must be distinctly different in color and design.

(2) All biological products in USDA-licensed establishments, whether licensed by USDA or by the State, shall be prepared only in locations indicated